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10/089,641	05/03/2002	Dae Gun Kim	6181/OK439	3102

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S Peter Ludwig
Darby & Darby
Post Office Box 5257
New York, NY 10150-5257

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,641	KIM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/5/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-37* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 11-37 are pending.

Applicants' amendment to claims 19 and 20 and the addition of claims 21-37 in paper filed on 10/5/04 is acknowledged and considered.

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 10/5/04 is acknowledged.

Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/5/04.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the method claims 19-37 were not filed in the original application with the original oath and there is no statement or indication in the file of record that all of the inventors listed in the original oath were the inventors of the newly added method claims.

Claim Objections

Applicant is advised that should claim 19 be found allowable, claim 35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The recitation of "in vivo" in claim 35 is already encompassed in the claim from which it depends (Claim 19). Claim 19 is a method of treating a mammal comprising directly administering to the mammal a recombinant adenovirus. This recitation in claim 19 already limits the claim to only in vivo embodiment.

Claim 34 is objected to because of the following informalities: Claim 34 is dependent on dependent claim 24 and the claim is not listed after claim 24.

A claim that depends from a dependent claim should not be separated from that dependent claim by any claim that does not also depend from that dependent claim. See MPEP 608.01(n), part IV.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 25, 27, 30, 31, 33, 34, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new claims 24, 25, 27, 30, 31, 33, 34, and 37 are not supported by the as-filed specification. There appears to be no written description of a method of in the application as filed. See MPEP § 2163.06. Page 9, line 8-page 10, line 7; Figure 4-6, and Examples 6 and 7 are cited for support of the new claims by applicants, but do not disclose the newly claimed method. On pages 9-10, the applicants contemplate using recombinant adenovirus for the treatment of variety of cancers, including cervical cancer, breast cancer, and colon cancer. On pages 9-10, applicants further teach that MCF7 cell derived from the breast cancer, HeLa cell line, derived from the cervical cancer and RKO cell line derived from colon cancer, were the cancer cell lines used in the examples and human colon cancer cells were used as an animal model in the present invention. Example 6 and Figures 4-6 are directed in vitro experiments using these cell lines. Example 7 teaches a mouse model transplanted with human colon cancer cells. The specification provides support for treating cervical cancer, breast cancer and colon cancer in the claimed methods. However, the specification does not generally (or even in passing) describe treating breast cancer where the breast cancer tumor cells express the estrogen receptor or are metastatic. The specification does not generally (or even in passing) describe treating colon cancer wherein the colon cancer is metastatic. Taking characteristics of an individual embodiment and making that characteristic the basis of a generic claim without

further supporting disclosure is not in compliance with the written description requirement. See *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481, 1487 (CAFC 2000). The new claims are considered essential subject matter that was not disclosed in the specification. In addition, the in vitro examples using PKO, MCF7, and HeLa cell lines in the specification do not support the in vivo methods of treating either breast cancer tumor cells that express estrogen receptor or metastatic breast cancer or a metastatic colon cancer. The properties of tumors *in vivo* are different than tumor cell lines (Gomez-Navarro et al., European Journal of Cancer, Vol. 35, pp. 867-885, 1999).

Applicants cite three abstracts by Yu, Spiryda, and Bresalier for support that MCF-7, He-La, and HM-7 colon cells used in the experiments are metastatic and cite Welshonds' abstract for support of the claims to "estrogen receptor" expressing tumor cells.

The citation of the abstracts by applicants in their arguments is moot because the specification as filed does not disclose generic embodiments, when breast cancer is metastatic or the breast cancer tumor express estrogen receptors. In addition, the specification as filed does not disclose generic embodiments, when colon cancer is metastatic colon cancer.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

It is apparent that the applicants at the time the invention was made did not intend or contemplate using the methods cited in the claims as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the claimed

methods as set forth in the claims 24, 25, 27, 30, 31, 33, 34, and 37, as it is now claimed, at the time the application was filed.

Claims 19-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cancer in a mammal comprising directly administering to a tumor in the mammal a recombinant adenovirus containing expression vector comprising P972 gene and a promoter operably linked to the P972 gene and an in vitro method of inhibiting growth of mammalian tumor cell comprising contacting the tumor cell with the recombinant adenovirus, does not reasonably provide enablement for a method of treating cancer in a mammal comprising contacting tumor cells or directly administering said recombinant adenovirus to mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants claim methods (claims 19-37) for treating tumor cells in a mammal comprising directly administering to a mammal or contacting said tumor cells with a recombinant adenovirus containing an expression vector comprising P972 gene and a promoter operably linked to the P972 gene. In addition, claims 28-33, 35, and 37 also read on an in vitro method of inhibiting tumor cells using the recombinant adenovirus.

At the time the application was filed, gene therapy was considered to be unpredictable due to significant problems in several areas. The state of the art, exemplified by Anderson et al.,

Nature, Vol. 392, pp. 25-30, 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

1) The type of vector and amount of DNA constructs to be administered,

2) The route and time course of administration, the sites of administration, and successful uptake of the claimed DNA at the target site;

3) The trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA product, the amount and stability of the protein produced, and

4) What amount of the expressed proteins considered to be therapeutically effective for a DNA therapy method.

In addition, all of these issues differ dramatically based on the specific vector used, the route of administration, the animal being treated, therapeutically effective amount of the DNA, and the disease being treated.

Anderson teaches that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact on the treatment of disease, and that several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (pp. 25-30).

Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack the basis understanding of how vectors should be constructed what regulatory sequences are appropriated for which cell types (page 30, column 1, last paragraph). Furthermore, Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target

tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2).

In further view of the doubts expressed above by Anderson and Verma, the state of the art for cancer gene therapy as discussed by Vile et al., (Gene Therapy, Vol. 7, pp. 2-8, 2000). Vile teaches:

> The problems which gene therapy for cancer will take into the next millennium focus far less on the choice of therapeutic gene(s) to be used than on the means of delivering them. There is already a battery of genes that we know are very effective in killing cells, if they can be expressed at the right site and at appropriate levels. None the less, until the perfect vector is developed, the choice of gene will remain crucially important in order to compensate for the deficiencies of the vectors we currently have available (page 2, 1st paragraph, left column). Whatever its mechanism, no single genes can be a serious contender unless it has a demonstrable bystander effect (page 2, right column). The requirement for such a bystander effect stems directly from the poor delivery efficiency provided by current vectors (page 2, right column).
>
> A genuine ability to target delivery systems to tumor cells distributed widely throughout the body of a patient would simultaneously increase real titers and efficacy. In truth, no such systemically targeted vectors exist yet. Injection of vectors into the bloodstream for the treatment of cancer requires not only that the vectors be targeted (to infect only tumor cells) but also that they by protected (from degradation, sequestration or immune attack) for long periods of time so that they can reach the appropriate sites for infection. Moreover, having reached such sites, the vectors must be able to penetrate into the tumor from the bloodstream before carrying out their targeted infection (page 4, bottom left column and top right column).

Thus, at the time the application was filed, the state of the art for gene therapy was considered highly unpredictable.

For additional reviews of the unpredictability of the gene therapy art, see Gomez-Navarro et al., European Journal of Cancer, Vol. 35, pp. 867-885, 1999; McNeish et al., Gene Therapy, pp. 1-7, 2004; Green et al., Cancer Gene Therapy, 9:1036-1042, 2002; Alemany et al., Nature Biotechnology, 18:723-727, 2000; Gromeier, ASM News, 68:438-445, 2002.

With respect to claims 28-33, 35, and 37 reading on an in vitro method, the specification is enabled for the in vitro method. However, claims 28-37 also read on an in vivo treatment method. Furthermore, with respect to the treatment method in claims 19-37, the specification is only enabled for cancer therapy comprising directly administering to tumor cells said recombinant adenovirus comprising P972 gene and a promoter operably linked to the gene and not for the full breadth of the claimed method because it would have taken one skilled in the art an undue and excessive amount of experimentation to practice using a recombinant adenovirus in a genus of administration routes. The art of record teaches that cancer gene therapy is unpredictable. The unpredictability taught by the art of record involves poor and inefficient delivery of adenovirus to target a tumor, host immune response which limit the ability of the adenovirus to infect a tumor, failure to efficiently infect certain tumors which lack adenoviral receptor CAR, promiscuous tropism which causes uncontrolled adenoviral infection and gene transfer into normal bystander cells, uptake intake into the liver of adenovirus instead of uptake into target tumor when the virus is systemically (e.g., intravenous administration) delivered to a patient.

With regard to previous experience with adenovirus to treat cancer, McNeish et al., (supra) teaches that in 93 patients receiving adenoviral particles, no objective clinical response were seen patients receiving the virus alone but that some responses were seen in patients receiving the virus in combination with chemotherapeutic agents. McNeish further teaches that: Although targeting tumor suppressor gene pathways is an attractive and logical strategy for cancer gene therapy, results from clinical trials have not mirrored the preclinical studies.

Clearly, the ability to induce cell cycle arrest and apoptosis in vitro or growth arrest in mouse xenografts does not guarantee response in clinical trials. See page 5.

This is further supported by Gomes-Navarro et al., (supra), who teaches that, "the spontaneous behavior of human tumors is somewhat different for that of malignant cells in vitro, and from that of experimental tumors in animal models."

The applicants teach that recombinant adenovirus coding for P972 can kill tumor cells in vitro; however, the art of record and the specification do not teach one skilled in the art how to correlate between results obtained in vitro studies set forth in the specification with results which the skilled artisan would reasonably expect to see in vivo. Furthermore, oncolysis in a cell line does not provide a nexus to treatment of tumors in vivo because the art of record and the specification do not provide sufficient guidance and/or factual evidence that killing tumor cells in vitro reasonably extrapolates to treatment of a tumor in vivo because killing tumor cells in vitro does not indicate that the number of tumor cells killed in a tumor in vivo is more than the number of new tumor cells in the tumor.

Furthermore, it would take one skilled in the art an undue amount of experimentation to determine what route of administration (*e.g.* intravenous, dermal, nasal, rectal, vaginal, inhalation, or topical administration) other than direct administration to the tumor cells would result in a therapeutic response using the recombinant adenovirus encoding P972. The applicants teach that P972 inhibits tumorigenicity of tumor cell lines or tumor colon cell line in nude mice by direct administration of the adenovirus. The state of the art for the route of administration for gene therapy as exemplified by Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target

tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). The specification supports the unpredictability in the art by stating that to overcome this problem to a certain extent direct delivery to the defective cells is used (page 3). In view of the art of record, it is not apparent to one skilled in the art how to reasonably extrapolate from direct administration to tumor cells to a genus of administration routes to generate a therapeutic response in a mammal with cancer.

Given the above analysis of the factors, it is concluded that the as-filed specification and the claims coupled with the art of record, at the time the invention was made, only provide sufficient guidance and/or evidence to reasonably enable a method of treating cancer in a mammal comprising directly administering to a tumor in the mammal a recombinant adenovirus containing expression vector comprising P972 gene and a promoter operably linked to the P972 gene and an in vitro method of inhibiting growth of mammalian tumor cell comprising contacting the tumor cell with the recombinant adenovirus and not for the full breadth of the claimed invention. Given that cancer gene therapy wherein an adenovirus is employed to treat a tumor in an individual was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to a cancer gene therapy effect produced by any adenovirus cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicants' disclosure and the unpredictability of cancer gene therapy

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites the limitation "wherein the inhibiting tumor growth is in vivo" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Oncogene, 18, 4899-4907, 1999) taken with Gomez-Navarro et al. (European Journal of Cancer, Vol. 35, pp. 867-885, 1999).

Zhang teaches a method of suppressing colony formation of human tumor cells using expression vectors containing CR6, MyD118, Gadd45, or p53 cDNA (page 4904). The instant specification teaches that P972 is also referred to as Gadd45-gamma, CR6 or OIG37 (see abstract). However, Zhang does not specifically teach using a recombinant adenovirus containing an expression vector comprising P972 gene and a promoter operably linked to the P972 gene.

However, at the time the invention was made, Gomez-Navarro teaches that adenoviral vectors have been used as a gene transfer system for treating cancer (page 876).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang and Gomez-Navarro, namely to use a recombinant adenovirus comprising an expression vector comprising P972 gene in a method of reducing cell growth in a tumor cell line. One of ordinary skill in the art would have been motivated to combine the teachings because adenoviral vectors are well known in the art for delivering an expression vector to tumor cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 28, 29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takekawa et al. (Cell, 95, 521-530, 1998, Ref. 1) taken with Gomez Navarro et al. (European Journal of Cancer, Vol. 35, pp. 867-885, 1999).

Takekawa teaches a method of reducing the number of HeLa cells using expression vectors containing GADD45-like proteins, Gadd45beta or gamma (page 525). The instant specification teaches that P972 is also referred to as Gadd45-gamma, CR6 or OIG37 (see abstract). However, Takekawa does not specifically teach using a recombinant adenovirus containing an expression vector comprising P972 gene and a promoter operably linked to the P972 gene.

However, at the time the invention was made, Gomez-Navarro teaches that adenoviral vectors have been used as a gene transfer system for treating cancer (page 876).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Takekawa and Gomez-Navarro, namely to use a recombinant adenovirus comprising an expression vector comprising P972 gene in a method of reducing cell growth in a tumor cell line. One of ordinary skill in the art would have been motivated to combine the teachings because adenoviral vectors are well known in the art for delivering an expression vector to a tumor cell.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER